

# Plain Language Summary Clinical Trial

## Plain Language Summary of Publication

### Clinical activity and safety of the anti-PD-1 monoclonal antibody dostarlimab for patients with recurrent or advanced dMMR endometrial cancer

Ana Oaknin, Anna V Tinker, Lucy Gilbert, Vanessa Samouëlian, Cara Mathews, Jubilee Brown, Maria-Pilar Barretina-Ginesta, Victor Moreno, Adriano Gravina, Cyril Abdeddaim, Susana Banerjee, Wei Guo, Hadi Danaee, Ellie Im & Renaud Sabatier

First draft submitted: 12 May 2021; Accepted for publication: 7 July 2021; Published online: 24 August 2021



#### Summary

This document provides a short summary of the GARNET trial which was published in *JAMA Oncology* in October 2020. At the end of this document, there are links to websites where you can find more information about this study.

The trial enrolled adult participants with advanced solid tumors. This report is restricted to patients with a particular type of endometrial cancer that has a deficient mismatch repair (dMMR) status. Patients received a trial treatment called dostarlimab (also known by the brand name Jemperli). In the US, dostarlimab is approved as a single therapy in adult patients with dMMR recurrent or advanced endometrial cancer that has progressed on or after platinum-based chemotherapy. In the EU, dostarlimab is approved as a single therapy in adult patients with recurrent or advanced dMMR/microsatellite instability-high (MSI-H) endometrial cancer that has progressed on or after treatment with a platinum-containing regimen. The GARNET trial looked at dostarlimab given intravenously to patients with dMMR endometrial cancer from 7 countries. The trial showed that dostarlimab was successful in shrinking the tumor in 42% of these patients. In general, the percentage of participants who experienced medical problems (referred to as side effects) was low and within expectations for this type of treatment.

How to say....

• **Dostarlimab:** doh-STAR-luh-mab

• **Endometrial:** en-dow-MEE-tree-uhl

Plain language summary clinical trial refers to the practice of summarizing the outcomes and key findings of clinical trials in language that is easily understandable to the general public. These summaries aim to bridge the gap between complex medical jargon and the layperson's understanding, ensuring that trial participants, patients, and the broader community can grasp the implications of the research. As clinical trials are fundamental in advancing medical science, the effective communication of their results is crucial in fostering trust, promoting informed decision-making, and enhancing patient engagement.

## Importance of Plain Language Summaries

The significance of providing plain language summaries in clinical trials cannot be overstated. These summaries serve multiple purposes:

### 1. Enhancing Public Understanding

Clinical trials often involve intricate methodologies, statistical analyses, and scientific terminologies that can be confusing for those without a medical background. By offering plain language summaries, researchers can:

- Make findings accessible to a wider audience.
- Help individuals understand the relevance of the research to their health.

- Empower patients to make informed choices regarding participation in trials or treatment options.

## **2. Encouraging Patient Participation**

When potential participants understand the purpose and outcomes of a clinical trial, they may be more inclined to enroll. Plain language summaries can:

- Reduce anxiety and uncertainty about the trial process.
- Clarify the benefits and risks associated with participation.
- Foster a sense of trust in the research community.

## **3. Promoting Transparency**

Transparency in clinical research is crucial for ethical considerations. Plain language summaries contribute to this transparency by:

- Providing clear information about trial results to patients and the public.
- Allowing for easier monitoring of research integrity and accountability.
- Encouraging open discussions regarding the implications of the findings.

## **4. Supporting Healthcare Decision-Making**

Healthcare professionals often rely on clinical trial data to inform their practices. Plain language summaries can:

- Assist healthcare providers in communicating trial results to patients.
- Provide a concise overview of findings that can be easily referenced in clinical decision-making.
- Help bridge the gap between scientific research and practical application in patient care.

# **Elements of an Effective Plain Language Summary**

To create an effective plain language summary, certain elements should be included to ensure clarity and comprehensibility:

## **1. Title**

The title should be straightforward and descriptive, reflecting the main focus of the clinical trial. It should avoid jargon and be easily understood by the general public.

## **2. Introduction**

This section should provide background information on the condition being studied and the purpose of the trial. Key points to cover include:

- The disease or health issue at hand.
- Why the research is important.
- What the trial aims to achieve.

## **3. Methodology**

While the methodology section in a traditional clinical trial report may be dense, the plain language summary should simplify this information. It should explain:

- The type of study (e.g., randomized controlled trial, observational study).
- How participants were selected.
- The interventions or treatments tested.

## **4. Key Findings**

This section is crucial as it presents the results of the trial. It should highlight:

- Primary outcomes (e.g., effectiveness of the treatment).
- Any secondary outcomes or additional findings.
- Statistical significance in a way that is easily digestible.

## **5. Implications of the Findings**

Discuss the potential impact of the results on patients, healthcare, and future research. This may include:

- How the findings could influence treatment options.
- Recommendations for patients or healthcare providers.
- Suggestions for further research based on the outcomes.

## **6. Conclusion**

Summarize the main points of the trial and re-emphasize its importance to the audience. This section should leave readers with a clear understanding of what the trial achieved and its relevance to real-world health issues.

# Challenges in Creating Plain Language Summaries

Despite the clear benefits, there are several challenges associated with crafting effective plain language summaries for clinical trials:

## 1. Balancing Detail and Simplicity

One of the primary challenges is finding the right balance between providing sufficient detail and maintaining simplicity. Researchers must:

- Avoid oversimplification that could lead to misinterpretation.
- Ensure that essential information is conveyed without overwhelming the reader.

## 2. Addressing Diverse Audiences

Plain language summaries must cater to a diverse audience with varying levels of health literacy. Strategies to consider include:

- Using clear and concise language.
- Avoiding technical terms or explaining them when necessary.
- Incorporating visuals or infographics to aid understanding.

## 3. Ensuring Accuracy

Maintaining accuracy while simplifying complex information is crucial. Researchers should:

- Collaborate with communication specialists or health literacy experts.
- Review summaries with stakeholders, including laypersons, to ensure clarity and correctness.

# Best Practices for Writing Plain Language Summaries

To maximize the effectiveness of plain language summaries, the following best practices should be followed:

## 1. Use Clear Language

Choose words that are commonly understood and avoid jargon. If technical terms are necessary, they should be clearly defined.

## **2. Be Concise**

Aim for brevity while ensuring that all essential information is included. Use short sentences and paragraphs to enhance readability.

## **3. Incorporate Visuals**

Visual aids such as charts, graphs, and infographics can help clarify complex information, making it easier for readers to grasp key findings at a glance.

## **4. Engage Stakeholders**

Involve patients, caregivers, and healthcare professionals in the development of plain language summaries. Their feedback can provide insights into what information is most relevant and how it should be presented.

## **5. Evaluate and Revise**

After drafting a plain language summary, evaluate its effectiveness through user testing. Gather feedback and make necessary revisions to improve clarity and comprehension.

## **Conclusion**

In summary, the importance of plain language summary clinical trial extends beyond mere communication; it plays a vital role in enhancing public understanding, promoting patient participation, and ensuring transparency in clinical research. By adhering to best practices and overcoming challenges associated with creating these summaries, researchers can effectively convey their findings to a broader audience, ultimately contributing to improved patient care and informed decision-making in healthcare. As the landscape of clinical research continues to evolve, the commitment to clear communication will remain essential in bridging the gap between science and society.

## **Frequently Asked Questions**

### **What is a plain language summary in clinical trials?**

A plain language summary is a brief explanation of a clinical trial's purpose, methods, results, and implications, written in clear, non-technical language that is easily understandable by the general public.

## Why are plain language summaries important in clinical research?

Plain language summaries are important because they enhance public understanding of clinical research, promote transparency, and help patients make informed decisions about their health care options.

## Who is the target audience for plain language summaries?

The target audience for plain language summaries includes patients, caregivers, healthcare providers, and the general public who may not have a scientific background.

## How can plain language summaries improve patient engagement in clinical trials?

Plain language summaries can improve patient engagement by providing clear information about the trial's relevance, potential benefits, and risks, thereby empowering patients to participate and ask informed questions.

## What are some best practices for writing effective plain language summaries?

Best practices for writing effective plain language summaries include using simple vocabulary, avoiding jargon, organizing information logically, using visuals when appropriate, and ensuring the text is concise and focused on key points.

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Unlock the essentials of clinical trials with our plain language summary. Understand key findings and implications easily. Learn more for better health decisions!

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